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**Award Number:** W81XWH-11-2-0106

**TITLE:** Post Admission Cognitive Therapy (PACT) for the Inpatient Treatment of Military Personnel with Suicidal Behaviors: A Multi-Site Randomized Controlled Trial

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**CONTRACTING ORGANIZATION:**

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**REPORT DATE:** February 2014

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

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<b>REPORT DOCUMENTATION PAGE</b>				<i>Form Approved</i> <b>OMB No. 0704-0188</b>	
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<b>1. REPORT DATE (DD-MM-YYYY)</b> 01-01-2014		<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED (From - To)</b> 01-01-2013-01-01-2014	
<b>4. TITLE AND SUBTITLE</b>  Post Admission Cognitive Therapy (PACT) for the Inpatient Treatment of Military Personnel with Suicidal Behaviors: A Multi-Site Randomized Controlled Trial				<b>5a. CONTRACT NUMBER</b>	
				<b>5b. GRANT NUMBER</b> W81XWH-11-2-0106	
				<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b>  Marjan G. Holloway, Ph.D. Laura L. Neely, Psy.D. marjan.holloway@usuhs.edu				<b>5d. PROJECT NUMBER</b>	
				<b>5e. TASK NUMBER</b>	
				<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  Henry M. Jackson Foundation for the Advancement of Military Medicine Rockville, Maryland 20852				<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> U.S. Army Medical Research                      Fort Detrick, MD 21702-5012 And Materiel Command				<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
				<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for public release; distribution unlimited.					
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> The broad objective of this study is to evaluate the efficacy of a cognitive behavioral intervention, titled, <i>Post Admission Cognitive Therapy</i> (PACT), for military personnel psychiatrically hospitalized, with either a recent or a lifetime suicide attempt. The research design is a multi-site, single-blind, randomized controlled trial (RCT). A total of 218 individuals who are over the age of 18, English speaking, and willing to provide informed consent will be recruited from the inpatient psychiatric units at the Walter Reed National Military Medical Center and the Fort Belvoir Community Hospital. Participants will be randomized into one of two conditions: (1) [Post Admission Cognitive Therapy (PACT) + Enhanced Usual Care (EUC)] or (2) Enhanced Usual Care (EUC). Individuals randomized into PACT+EUC will participate in the study assessments, receive six 60-90 minute individual face-to-face PACT sessions provided during their inpatient stay, up to a maximum of four 60-minute phone PACT booster sessions during the 3 months post hospital discharge, and case management for 12 months. Individuals randomized into the control condition (EUC) will not receive the study intervention; they will receive the usual care provided in the inpatient setting, participate in study assessments, and receive case management services for 12 months. Patients in both conditions will be assessed on the dependent measures at baseline and at 1-, 3-, 6-, and 12-months. Delivering a brief intervention during hospitalization, followed by an aftercare component, targets individuals at high risk for future suicide, specifically young, psychiatrically hospitalized adults under the direct stress of a military career.					
<b>15. SUBJECT TERMS</b> Suicide Prevention, Acute Care, Inpatient Treatment, Cognitive Behavior Therapy					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  UU	<b>18. NUMBER OF PAGES</b>  34	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC
<b>a. REPORT</b>  U	<b>b. ABSTRACT</b>  U	<b>c. THIS PAGE</b>  U			<b>19b. TELEPHONE NUMBER (include area code)</b>

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## Introduction

**Background:** Suicide remains a serious national public health problem and has become a leading cause of death in the United States military. To date, there is no evidence-based civilian or military inpatient interventions aimed at the reduction of suicide behavior. Our proposal addresses this important gap and aims to evaluate an innovative suicide intervention, *Post Admission Cognitive Therapy* (PACT). Left untreated, severe suicide ideation and/or suicide attempts that require psychiatric hospitalization may place an individual at a lifetime risk for increased psychopathology, subsequent suicide behavior, and death.

**Objective:** The broad objective of the proposed study is to empirically evaluate the efficacy of a cognitive behavioral intervention, titled, *Post Admission Cognitive Therapy* (PACT), for military service members psychiatrically admitted for inpatient care due to a suicide-related event with either a recent or a lifetime suicide attempt.

**Specific Aims:** To evaluate the efficacy of PACT plus Enhanced Usual Care (EUC) versus EUC for the prevention of suicide in psychiatrically hospitalized military personnel at follow-up (1, 3, 6, and 12-month) on (1) incidence of repeat suicide attempt(s) and number of days until a repeat suicide attempt (primary outcomes), and (2) psychiatric symptoms (depression, trauma, sleep, suicide ideation), repeat number of psychiatric hospitalization(s), hope for one's future, and acceptability of treatment (as measured by time to linkage to specialty care, attitudes toward seeking help for mental health issues, and subsequent mental health service utilization) (secondary outcomes). We expect that adults in the PACT+EUC (experimental) condition compared to those in the EUC (control) condition will show favorable outcomes on both primary and secondary measures.

**Study Design:** The research design is a multi-site, single-blind, randomized controlled trial (RCT). A total of 218 individuals who are over the age of 18, able to communicate in English and willing to provide informed consent will be recruited from the inpatient psychiatric units at Walter Reed National Military Medical Center (WRNMMC) and Fort Belvoir Community Hospital (FBCH). Participants will be randomized into one of two conditions: (1) [Post Admission Cognitive Therapy (PACT) + Enhanced Usual Care (EUC)] or (2) Enhanced Usual Care (EUC). Individuals randomized into PACT+EUC will participate in the study assessments, receive six 60-90 minute individual face-to-face PACT psychotherapy sessions provided during their inpatient stay, up to a maximum of four 60-minute phone PACT booster sessions during the 3 months post hospital discharge, and case management services for 12 months. Individuals randomized into the control condition (EUC) will not receive the study intervention; they will receive the usual care provided in the inpatient setting, participate in study assessments, and receive case management services for 12 months. Patients in both conditions will be assessed on the dependent measures at baseline and at 1, 3, 6, and 12-month follow-up intervals.

**Relevance:** Delivering a brief and possibly potent psychotherapeutic intervention during a psychiatric inpatient hospitalization followed by an aftercare component aims to directly target individuals at high risk for future suicide behavior, specifically young, psychiatrically hospitalized adults under the direct stress of a military career. The development and empirical validation of an inpatient cognitive behavioral treatment is a significant endeavor in our national as well as Department of Defense (DoD) suicide prevention efforts. If *Post Admission Cognitive Therapy* is found to be efficacious, the intervention can be subsequently disseminated to inpatient settings as the standard of care for military personnel admitted for suicide-related events.

## Body

During each quarter of the past year, we engaged in the following activities: (1) working directly with the Henry Jackson Foundation (HJF) to ensure the timely processing of the sub-awards and contracts for the study (Duke University; KAI, Inc.; and University of Michigan); (2) working directly with the regulatory boards at the Uniformed Services University of the Health Sciences (USUHS), Walter Reed National Military Medical Center (WRNMMC), Ft. Belvoir Community Hospital (FBCH), Duke University IRB, Michigan University IRB, and the Human Research Protections Office (HRPO) at the USAMRMC Office of Research Protections to prepare all required IRB-related documentation; (3) continuing the process of new employee selection and recruitment; (4) providing training to newly hired staff; (5) coordinating with various study collaborators on research efforts; (6) purchasing study-related materials and supplies; (7) refining the baseline and follow-up assessment protocols, standard operating procedures, and treatment protocols; (8) maintaining regular contact with collaborators; and (9) working with the KAI team to develop electronic study related forms and questionnaires, problem solving study-related challenges, and planning for the adverse event reporting/tracking for the multi-site RCT.

Quarter 1 was heavily focused on treatment development and the training of staff for the PACT RCT implementation. During the second quarter of Year 3, the study PI presented at the “In Progress Review” Meeting held May, 2013. Quarter 3 was heavily focused on finalizing the KAI database and electronic forms. Quarter 4 was focused mostly on beginning recruitment and refining the study procedures.

A brief summary of the progress made on all Year 3 tasks listed on the original Statement of Work is provided below.

### **Overview of Study Activities for Quarters 1-4**

#### **Performance Period: February 1, 2013 to January 31, 2014**

Below is a list of the tasks we have made progress on during Year 3. These tasks correspond to the Statement of Work, Years 2-4. More detail about each task is provided below.

- ✓ Schedule regular conference calls for key study collaborators
- ✓ Submit appropriate IRB applications for Site 1 (WRNMMC) study implementation
- ✓ Submit appropriate IRB applications for Site 2 (FBCH) study implementation
- ✓ Interview, select, and hire qualified study personnel for both implementation sites
- ✓ Develop study forms, database/randomization, risk management guide, and regulatory binders
- ✓ Prepare comprehensive baseline and follow-up assessment guide and training procedures
- ✓ Prepare comprehensive treatment guide, case management, and training procedures
- ✓ Prepare final version of adherence rating forms
- ✓ Conduct training seminars for study assessment and treatment procedures
- ✓ Begin recruitment of training cases and study participants at Site 1 (WRNMMC)
- ✓ Begin recruitment of training cases and study participants at Site 2 (FBCH)
- ✓ Continue with recruitment of study participants at both study sites
- ✓ Conduct follow-up phone and web-based assessments

- ✓ Offer study case management
- ✓ Conduct competency and adherence ratings
- ✓ Attempt to meet a “set” recruitment goal
- ✓ Setup annual meetings for study collaborators
- ✓ Hold DSMB annual meetings
- ✓ Prepare and submit all applicable quarterly and annual reports

### **Scheduled regular conference calls for key study collaborators**

The PI of the study, Dr. Marjan Holloway, along with the study Coordinator, Dr. Laura Neely held regular meetings with Dr. David Goldston and Dr. Cheryl King on a bi-weekly basis for 1 hour. These meetings were used to discuss implementation challenges, methodology issues, and risk management/adverse event reporting. Meeting minutes were recorded for each conference call to document decisions made.

### **Submitted appropriate IRB applications for Sites 1 & 2**

On September 13, 2013, we submitted continuing review packages to (a) the WRNMMC Lead site, (b) the WRNMMC Local recruitment site, and (c) the FBCH Local recruitment site. In addition to the required continuing review documents, the submissions included a minor amendment to update current personnel working on the project. Each site received approval on September 26, 2013. Next, we submitted the continuing review to the USUHS IRB on October 10, 2013. Secondary concurrence was received from the USUHS IRB on October 11, 2013 and continuing review approval from HRPO was received on November 6, 2013.

### **Interviewed, selected, and hired qualified study personnel for both implementation sites**

During Year 3, we hired a post-doctoral fellow, Dr. Jennifer Tucker, to provide evening and weekend coverage. Dr. Tucker completed in-processing at both WRNMMC and FBCH and has seen training cases and formal cases at each site. We have also hired 2 master’s level research assistants to provide case management at both sites. One of the research assistants provides evening and weekend coverage to allow for maximum coverage and recruitment of cases at both sites.

### **Developed study forms, database/randomization, risk management guide, & regulatory binders**

Quarter 3 was heavily focused on finalizing the study forms and study database. The research team held regular conferences calls with KAI to make progress on this task. By the end of Year 3, significant progress has been made on the completion of the study forms and database. The study Standard Operating Procedures (SOP), the Risk Management Guide, and the Adverse Event Reporting SOP were finalized during this reporting period. Mr. Robert Wheeler, IRB Coordinator, continues to work on finalizing the regulatory binder. He has gathered all necessary documents and is working to make a hard copy and an electronic copy accessible to all lab members. We hope to have all of the remaining items finalized during the next reporting period.

### **Prepared comprehensive guides and training procedures**

During this reporting period we finalized the comprehensive guides and training procedures.

### **Prepared final version of adherence rating forms & conducted review of competency and adherence ratings**

The research team is actively working on modifying the Cognitive Therapy Rating Scale for the purposes of PACT. This will then be used while listening to approximately 10% of the cases to ensure fidelity and integrity of the treatment protocol. We hope to have this finalized in the next reporting period.

### **Conducted training seminars for study assessment and treatment procedures**

Various trainings were held throughout the year that covered a wide range of RCT related activities, such as

- PACT intervention delivery
- How to gather patient information during morning report for recruitment while maintaining PHI and confidentiality
- Safety on an inpatient unit
- Administration and logistical issues regarding the consenting procedures, baseline assessment, and follow up procedures
- Motivational interviewing and booster session delivery
- Administration, scoring, and interpretation of the Clinician Administered PTSD Scale (CAPS) conducted by Dr. Frank Weathers
- Administration, scoring, and interpretation of the Cornell Services Index (CSI) conducted by Dr. Joanne Sirey
- VPN Training for all personnel to become familiar with and learn how to review the electronic medical record
- End Note to assist in manuscripts
- Duke personnel received individualized role play mock assessment sessions and training for follow-up assessments and procedures conducted by Katheryn Ryan, MPH from the USUHS research team, based on experience with pilot studies
- USUHS Case Managers and Duke Assessors received training from KAI on how to enter data into the database
- USUHS and Duke staff were provided with Military Culture Training
- Each person received an individualized 2 hour training on Consenting Procedures
- Risk Management

The following list outlines weekly or biweekly trainings held throughout the year on a regular basis.

- Each case manager received a weekly individualized training on Consenting Procedures and Case Management from a doctoral level clinician
- Supervision for research personnel was held weekly for 1-2 hours to discuss cases and the application to the PACT RCT delivery
- Group supervision for clinical personnel was held weekly for 1-2 hours to discuss cases and the application to the PACT intervention delivery, supervised by licensed psychologists
- USUHS Study Clinicians along with Dr. Holloway participated in weekly 1-hour booster session supervision with Dr. Chery King and Dr. Steve Chermack from the University of Michigan, via conference call

### **Began recruitment of training cases and study participants at Site 1 (WRNMMC) and at Site 2 (FBCH)**

Study recruitment began June 24, 2013 for training cases. We recruited 4 training cases from WRNMMC and 2 training cases from FBCH. It was decided to recruit enough pilot cases to allow each USUHS Case Manager, Study Therapist, and Duke Assessor a chance to have a pilot case for training and problem solving. This provided valuable practice for the clinicians on the treatment protocol, for the case managers on consenting and case management procedures, for the follow-up assessors on telephone assessment procedures, and for data entry. We learned valuable lessons and were able to refine these procedures in preparation for formal recruitment. Formal recruitment began on November 15, 2013, after we received approval from the DSMB.

### **Continued with recruitment of study participants at both study sites**

We have continued with recruitment of study participants at both study sites, WRNMMC and FBCH. To date we have consented 11 study participants and randomized 9.

### **Conducted follow-up phone and web-based assessments**

The Duke assessors have continued to conduct follow-up phone assessments. Any issues with implementation or data entry were problem-solved during conference calls with the USUHS and KAI team. The assessors were trained on entering data via the web, on risk management SOP for the study, and on military culture.

### **Offered study case management**

Case managers continued to provide case management for study participants. Challenges were problem solved during a weekly PACT Team Meeting and on an individual basis with a doctoral level clinician supervising.

### **Attempted to meet a “set” recruitment goal**

Due to unforeseen obstacles and challenges, such as shorter length of inpatient stay, we have not met our recruitment goal. Based on the lower than expected recruitment rate we have considered and implemented a number of strategies to increase our recruitment number.

### **Current Recruitment Strategies**

*Morning Report Attendance:* A member of our research team participates in the morning report meeting at each site on a daily basis. The morning report meeting includes all attending physicians, residents, and interns, and provides updates on current patients and a brief case history of new admissions to the unit. Morning report is the primary source of information for eligible participants. The morning report manager uses this time to meet with the potential research participant’s attending physician or resident to request permission for approaching patients. During recent months, there has been increasing difficulty connecting with providers. At WRNMMC, providers often have staff-only meetings immediately following morning report which excludes the morning report manager. We have made efforts to connect with providers via phone or email, but continue to struggle with ensuring timely and effective communication given their demanding schedules.



*Research liaison:* In addition to morning report attendance at FBCH, we have a current FBCH staff member who acts as a liaison between the morning report manager and the attending physicians or residents. Her primary role on our project is to ensure that the physician or resident is made aware of potential patients and to coordinate communication between our research team and FBCH staff members. Unfortunately, we have lost a similar staff member at WRNMMC who left her position several months ago due to termination of her position.

### **Planned Recruitment Strategies**

*Provider Recruitment Education :* The PI (Dr. Holloway) and Clinical Coordinator (Dr. Neely) are planning to present an overview of the study for the new residents, during the morning report meeting. During this meeting, information on the research study, eligibility criteria, and the procedures associated with patient referral and recruitment will be discussed. This strategy was previously employed during the pilot studies and has proven an effective means of increasing enthusiasm and cooperation from the inpatient psychiatry staff, especially given the frequent turnovers. Furthermore, our morning report manager at WRNMMC has noticed that there appears to be a great deal of confusion about the “permission to approach process,” where providers aim to get permission for participation from the patient as opposed to simply asking for permission for our staff member to approach him or her to discuss the study.

### **Options Under Consideration for Increasing Recruitment Rate**

*Include dependents :* We are currently considering modifying the study criteria to include dependents over the age of 18. We believe this strategy will increase the number of potential patients as well as enhance the generalizability of the research findings.

*Increase site for recruitment:* We are currently considering adding one or two additional research sites. We have had a number of options including the North Carolina VA, the Portsmouth Naval Hospital, and Poplar Springs. We have consulted with the site PIs at WRNMMC and FCBH, COL Grammer and Dr. Weaver, to request site suggestions. At this time, we are first pursuing the possibility of adding the Washington, DC Veterans Medical Center as a third study site. We have also started to research local civilian inpatient hospitals in the area and may open the research study to include eligible civilians at a local site. Discussions are underway with the University of Arkansas Medical Sciences for the use of their inpatient unit as a fourth study site given that the leadership at this location is extremely interested to collaborate with our team and is planning to adapt the PACT intervention for group delivery.

*Modify inclusion criteria:* We are considering a modification to the study inclusion criteria such that service members admitted for suicide ideation can be entered into the study.

### **Setup annual meetings for study collaborators**

Scheduling for the annual meeting for study collaborators has been discussed on the weekly PI call between Dr. Holloway, Dr. Goldston, and Dr. King. We hope to have dates finalized and scheduled during the next reporting period.

### **Held DSMB annual meeting**

During Year 3, the PI, Dr. Marjan Holloway, recruited three members for the first the Data Safety Monitoring Board (DSMB). Dr. Kate Comtois is an Associate Professor at the Department of Psychiatry and Behavioral Sciences at Harborview Medical Center with expertise in psychotherapy and suicide prevention research and is serving as the DSMB chair. Dr. Thomas Ellis is the Director of Psychology at The Menninger Clinic with expertise in the delivery of psychotherapeutic interventions for inpatient settings as well as for suicide prevention. Dr. Cara Olsen is an Assistant Professor and Biostatistics Consultant at the Department of Preventive Medicine and Biometrics at Uniformed Services University, with expertise in statistical methods and procedures. Additionally, given Dr. Olsen's appointment at Uniformed Services University, she will have easy access to the study data (without the need for any data sharing agreements and regulatory board approvals) in case the DSMB requires any future independent study analyses. The members were provided with the following documents via email for preparation for the first meeting:

1. Approved Study Protocol
2. Approved Study Consent Form
3. IRB Approval Notices
4. Template of a Proposed DSMB Report

The first meeting was held on November 15, 2013. The primary objective of the first DSMB meeting was to review the DSMB expectations and decide upon a DSMB Report template that could be used for the duration of the study. Please see Appendix A for a copy of the DSMB Meeting 1 Minutes.

During the next reporting period, the USUHS research team will formulate a DSMB report and send to the DSMB members. At that time the DSMB will review the report, the preliminary data, and the adverse event log and decide if another meeting is warranted.

### **Prepared and submitted all applicable quarterly and annual reports**

During Year 3, all quarterly reports were submitted on time to the sponsor. Please note that Quarter 2 quarterly report was waived due to the In Progress Review meeting.

### **Additional Study-Related Activities**

#### **Implementation at Site 2: Fort Belvoir Community Hospital**

During Year 3 we worked diligently with the staff at FBCH to get this site up and running. We ordered furniture which included a desk and a locked lateral filing cabinet to store patient data, as well as a desktop computer. After a year-long wait, these items have been setup at the FBCH site. The USUHS research team was informed by Mr. Christopher Forte, Health System Specialist at FBCH, that the Fort Belvoir hospital requires a higher level security clearance than

what is needed at WRNMMC. Each of the USUHS research team members submitted the required paperwork. Four members of our research staff, including a licensed psychologist, a post-doctoral fellow, and 2 case managers were granted the higher level security clearance. Our staff made in-processing at FBCH a top priority, and completed all required paperwork, trainings, orientations, and clearances and we were approved to start seeing patients. This process has been tedious and very time consuming as we have had to tackle issues related to credentialing, time keeping for our hours based on the FBCH system, security clearances, and occupational health requirements. Given that our study staff members are government contractors serving in the role of researchers, we collaboratively worked with FBCH staff to best get our study up and running – and our staff functional per hospital guidelines.

#### **Began development of a PACT therapy workbook**

The USUHS Research team has bi-weekly meetings to develop a “Therapy Workbook” for our participants. This consists of handouts and supporting documents that will assist the clinician and participant during the PACT treatment delivery. We hope to have this finalized in the next reporting period. Our goal is to have this published as an addendum to the PACT Treatment Guide.

#### **Attended WRNMMC IRB Research Round Table meetings**

The WRNMMC IRB Research Round Table Meeting is sponsored by the WRNMMC IRB and the time is used to provide updates on any changes to the IRB or submission process and to answer any questions. Attendance is prioritized to maintain a relationship with the WRNMMC IRB and to ask pertinent questions to the functioning of our research study. Important updates are shared with the research team and incorporated into the infrastructure and regulatory binders. A member of the research team attended the WRNMMC IRB Research Round Table meetings once a month over the past year.

#### **Updated Clinical Trials.gov**

On October 25, 2013, Dr. Marjan Holloway (PI) updated this study on ClinicalTrials.gov. Please see Appendix B for a copy of the submission.

#### **Maintained contact with the study medical monitor**

Contact with the study Medical Monitor, Dr. Russell Carr is maintained via email and IRBNet as well as by phone as needed. Dr. Carr has kindly agreed to serve as the Medical Monitor for both sites, WRNMMC and FBCH.

#### **Held meeting with legal teams at WRNMMC and USUHS**

We have held a meeting with several lawyers from WRNMMC and USUHS in order to discuss and problem solve how to best send email reminders to study participants. Our discussions have focused on how to best protect patient confidentiality.

#### **Prepared application for Certificate of Confidentiality**

The application for Certificate of Confidentiality through the National Institute of Health has been prepared. We have contacted WRNMMC IRB to determine the authorizing official that needs to sign this document. We have had continuous delays with obtaining this signature, which has been due to the WRNMMC IRB developing a new system of obtaining Institution Official

signature. Over two months our team has continually contacted the WRNMMC IRB for updates and requests for signature, and yet we have not been able to make progress. We will continue to maintain contact and we hope to finalize the Certificate of Confidentiality over the next quarter.

### **Participated in the In-Progress Review (IPR) and North Atlantic Treaty Organization (NATO) Meetings**

The study was presented at the IPR annual meeting held in May, 2013. This provided an opportunity to exchange ideas with other investigators involved in military suicide prevention research. The NATO meetings were chaired by the study PI during which time the topic of military suicide across various NATO and partner countries was discussed. Attendance in these meetings were not supported by funding provided by this grant – however, the knowledge gained has been valuable in better understanding the unique needs of this highly vulnerable military population and the best practices employed by other nations.

### **Explored Adding Additional Sites**

As discussed above, recruitment numbers are lower than expected. Several factors have impacted this, including a new Chief of Inpatient Psychiatry, who has made it a goal of the unit to shorten the length of stay. This becomes an even smaller window of opportunity to provide the brief intervention, as intended. Therefore, additional sites are being explored to increase recruitment numbers.

The study PI, Dr. Holloway, consulted with the site PIs, Dr. Grammer (WRNMMC) and Dr. Weaver (FBCH), about other sites in the local area that would be amenable to research. The Washington DC VA Medical Center (DC VA) is located approximately 10 miles away from USUHS in Washington, D.C. and is one site under consideration. Dr. Holloway contacted the Inpatient Medical Director of the DC VA, Dr. Maria Llorente to set up a meeting to discuss possible research collaboration. Dr. Llorente was enthusiastic about the idea and a meeting is scheduled for early March. The results of this meeting will be reported in the next quarterly report. Moreover, the study PI, Dr. Marjan Holloway, provided training on CBT for suicide and PACT at the University of Arkansas for Medical Sciences the week of February 11<sup>th</sup>, and discussed the possibility of UAMS becoming another implementation site. This meeting occurred during the next reporting period for Y4, Q1, therefore the results of this meeting will be described in further detail during the next report. Briefly, UAMS expressed enthusiastic interest in the PACT study and becoming another implementation site. We hope to make progress in this direction during the next reporting period.

### **Prepared Memorandum of Understanding (MOU)**

The WRNMMC IRB had informed us that the CRADA submitted before the Base Realignment and Closure (BRAC) was null and void. The Study Coordinator spoke with Mr. Alan Cash in the Office of Research and Technology Applications at WRNMMC on April 30, 2013 and confirmed that a CRADA is not needed for this study. Mr. Cash formulated an MOU (between USUHS, WRNMMC, & FBCH) and forwarded it to USUHS to be approved. The USUHS Agreements Office (Ms. Malika Graham), USUHS legal counsel (Mr. Josh Girton), WRNMMC legal counsel (Ms. Dina Bernstein), and FBCH legal counsel (Mr. John Konst) all have reviewed and approved the MOU. It has been forwarded to the base commanders for signature. We hope to have this finalized in the next quarter.

## **Site Specific Reports of Activities in Collaboration with USUHS Team**

### **KAI Research, Inc.**

#### **A. Introduction – Contract Primary Objectives and Tasks**

KAI Research, Inc. (KAI), as the Data and Statistical Coordinating Center (DSCC) is responsible for providing coordination, data management, monitoring, and logistical support for this study.

#### **B. Brief Narrative of Tasks Accomplished**

KAI accomplished the following activities:

1. **Database Development** – Twenty forms were created in the KAI database. Requested revisions were made to an additional 24 forms. KAI provided templates for and programmed the screening module. KAI drafted specifications for five reports and drafted specifications and programmed the scoring for 28 forms in the database. KAI also made requested changes to the assessment sequence for follow-up visits in the database and added case management visits to the database.
2. **Study Forms** - KAI suggested changes and/or provided mocked up specs for 13 forms: Adverse Event form, Behavioral Observations – Telephone, Behavioral Observations - Face to Face forms, Case Management Contact log, Columbia Suicide Severity Rating Scale, Exit Interview, Mini International Neuropsychiatric Interview and Screen, Psychiatric Chart Review form, Scale for Suicidal Ideation, Study Termination form, Study Therapy Tracking, Subsequent Hospitalization Chart Review, and Subsequent Hospitalization Interview.
3. **Database Access** –
  - a. KAI delivered the live database to the USUHS team on June 24<sup>th</sup>.
  - b. KAI delivered the test database to the Duke team on June 25 and the live database on September 6<sup>th</sup>.
  - c. KAI provided database trainings on June 19, June 24, and July 2. Four USUHS staff members and four Duke staff members were trained during this reporting period on the data entry functions and capabilities of the database, and one USUHS staff member received a training refresher.
  - d. Since the delivery of the database in June, KAI has worked with USUHS and Duke staff to ensure it is accessible and functioning for each individual user.
4. **Statistical review** – KAI provided statistical feedback on the proposed stratification factors for the study. KAI provided recommendations on randomization block size.
5. **IVRS** - KAI programmed the Interactive Voice Recognition System (IVRS) and made updates as requested.
6. **Adverse Event Reporting Procedures** – KAI reviewed the adverse event and serious adverse event report form and procedures and held a call on October 7 with Rob Wheeler and Laura Neely to discuss and provide suggestions.

7. **DSMB** – KAI provided a sample DSMB charter and DSMB reporting table shells and attended the first DSMB meeting on November 15, 2013.
8. **Team Meetings** - KAI provided agendas and meeting minutes for teleconferences conducted on February 8, March 1, March 29, April 19, April 26, May 10, June 7, June 20, July 3, August 9, August 16, August 30, September 6, September 20, October 4, October 18, November 1, and November 8, and for an in-person meeting at KAI on May 24. KAI participated in the face-to-face meeting at USUHS on February 21 and presented the database at this meeting. Separate calls were also held to discuss the screening module on August 27 and the case manager calendar report on September 26. KAI held two budget calls with the PI, one on December 4 and the second on January 16.
9. **Project Management** - Celeste Crouse, the KAI project manager performed the following duties: served as the first line of contact for USUHS, supervised the entire KAI study team, and ensured that all deliverables to date were provided on time and of the highest quality. Amy Price supervised form creation, database and IVRS development, and data management activities.

**University of Michigan (Site PI: Cheryl King, Ph.D.)**

1. Obtained IRB approval for involvement in initial developmental phase of research project from the University of Michigan (UM) Medical School IRB (IRBMED).
2. Reviewed PACT protocol, including proposed baseline and follow-up assessment instruments, procedures, and timelines; Discussed these measures with UM co-investigators, Mark Ilgen, Ph.D., Paul Pfeffer, M.D., and Steve Chermack, Ph.D.; As a group, we reached a consensus on additional measures to propose for inclusion, which would assess areas related to social support and integration, use of prescription, drugs, readiness to engage in treatment, and personal expectations regarding safety from self-harm. Additional research on these measures was conducted and we shared information with the PACT project leadership and team. As a group, final decisions were made regarding assessment instruments and timelines via conference call.
3. Developed draft protocol for PACT telephone booster sessions for review and discussion with PACT leadership team. This involved (a) completing review of recent literature and published guidelines regarding telephone continuing care treatment, telephone booster sessions, and telephone-based case management in the treatment of adults with mental disorders, alcohol/substance use disorders, and related conditions; (b) group meetings with UM team to discuss and develop multiple initial drafts of protocol (goals, timeline for sessions, orientation to aftercare phase, session outlines) for review and input; and (c) group meetings with UM team to develop a draft Progress Assessment Form/aftercare action plan to be completed by the PACT clinician during telephone booster sessions.
4. Contributed to development of case management protocol, including dose (amount) and duration of case management to be offered to all study participants in both treatment arms.

5. Participated in Project Conference Calls with PI, Marjan Holloway, Ph.D., Co-Investigator, David Goldston, Ph.D., and key members of study team to discuss IRB applications, the timeline and plan for piloting telephone booster sessions, and a wide range of study issues.
6. Reviewed protocol and clinical documentation forms for PACT telephone booster sessions, making final edits. Developed draft versions of fidelity assessment tools for review at PACT Grant meeting with project leadership. These involved: (a) group meetings with University of Michigan team to discuss and fine-tune protocol and associated documents; (b) conference calls with project leadership to discuss feedback and incorporate input.
7. Developed draft plan for provision of clinical training to therapists who will implement PACT telephone booster sessions, including in-person training and plan for fidelity assessment and follow-up supervision/consultation.
8. Submitted IRB amendment to UM to enable our involvement in subject recruitment and implementation phase of study.
9. Reviewed and provided input on the Risk Management Guide.

**Duke University (Site PI: David Goldston, Ph.D.)**

1. Participated in regular conference calls with key study collaborators and contributed to the discussions on research design, baseline and follow-up assessment batteries, retention strategies, risk management, and other implementation related issues
2. Prepared and submitted all applicable quarterly and annual reports for Duke University site to HJF and the sponsor in coordination with the USUHS team
3. Held discussions with the Durham VA regarding the possibility of adding the site as the third recruitment site for the study
4. In collaboration with USUHS study PI and KAI, reviewed computerized study forms and electronic data entry forms and provided feedback
5. Prepared follow-up assessment guide and training procedures
6. Discussed training and risk management procedures to be used for Duke assessors who will be responsible for the blind follow-up assessments
7. Participated in trainings held on military culture, risk management, and data entry
8. Prepared and submitted applicable IRB amendments in coordination with USUHS team

## Key Research Accomplishments

The key research accomplishments over the past year include the following:

- ☑ Receipt of regulatory approvals on the study protocol from various boards
- ☑ Finalization of the study baseline and follow-up assessment battery and procedures
- ☑ Manualized drafts of study intervention, case management, and risk management SOPs
- ☑ Creation of study web-based electronic forms and database
- ☑ Training of personnel on assessment and intervention procedures
- ☑ Problem solving of implementation challenges and plans to add 3<sup>rd</sup> recruitment site
- ☑ Dissemination of the Air Force Guide on Suicide Risk Assessment, Management, and Treatment – much of the information on CBT provided in the Guide is based on our experiences gained during this study along with the previously CDMRP funded pilot trial on PACT
- ☑ Dissemination of information about PACT via national and international presentations

Given the magnitude of the public health problem of military suicide and the increasing rates of psychiatric hospitalizations within DoD, the development and empirical validation of an inpatient cognitive behavioral treatment is a significant suicide prevention endeavor. Delivering a brief and possibly potent psychotherapeutic intervention during a psychiatric inpatient hospitalization followed by an aftercare component aims to directly target individuals at high risk for future suicide behavior, specifically young, psychiatrically hospitalized adults under the direct stress of a military career.



# Reportable Outcomes

## **Section I. Manuscripts, Abstracts, Presentations**

### **Peer Reviewed Manuscripts**

1. Neely, L., Irwin, K., Carreno Ponce, J. T., Perera, K., Grammer, G., & Ghahramanlou-Holloway, M. (2013). Post Admission Cognitive Therapy (PACT) for the prevention of suicide in military personnel with histories of trauma: Treatment development and case example. Clinical Case Studies, 12(6), 457-473.
2. Kochanski-Ruscio, K., Carreno-Ponce, J. T., DeYoung, K., Grammer, G., & Ghahramanlou-Holloway, M. (in press). Diagnostic and psychosocial differences in psychiatrically hospitalized military service members with single versus multiple suicide attempts. Comprehensive Psychiatry.
3. Ghahramanlou-Holloway, M., Tucker, J., Neely, L. L., Carreno-Ponce, J. T., Ryan, K., Holloway, K., & George, B. (under review). Suicide risk among military women. Psychiatric Annals.
4. Ghahramanlou-Holloway, M., & Neely, L. L. (in preparation). Cognitive behavior therapy techniques for suicide prevention, Current Psychiatry.

### **Treatment Guide**

1. United States Air Force Medical Operations Agency. (2013). Air Force guide for suicide risk assessment, management, and treatment. San Antonio, Texas.

### **Invited Book Chapters**

1. Ghahramanlou-Holloway, M., & Balakar, J. (2013). Treating Veterans and military families. In G. P. Koocher, J. Norcross, & B. Greene (Eds.), Psychologists' desk reference: Third edition. New York: Oxford University Press.
2. Ghahramanlou-Holloway, M., Neely, L.L., & Tucker, J. (under review). Treating suicide risk in inpatient settings. In C. J. Bryan (Ed.), A guide to brief cognitive behavioral treatments for suicide risk across clinical settings. New York: Routledge.
3. Ghahramanlou-Holloway, M., Garrick, J., & Carreno-Ponce, J. T. (in press). Suicide-related ideation and behaviors in military women. In C. Ritchie and A. Naclerio (Eds.), Women at war: Medical and psychological issues. New York: Oxford University Press.
4. Ghahramanlou-Holloway, M., Tucker, J. & Neely, L. L. (in preparation). Post Traumatic Stress Disorder as a risk for suicide. In Comprehensive Guide to Post-Traumatic Stress Disorders. London: Springer.

## Conference Presentation and Published Abstracts

### *Invited Presentations*

1. Ghahramanlou-Holloway, M. (2013, March). Cognitive behavior therapy for the prevention of suicide. Invited presentation for behavioral health providers, Ft. Meade, MD.
2. Ghahramanlou-Holloway, M. (2013, May). Pilot trial of inpatient cognitive therapy for the prevention of suicide in military personnel with Acute Stress Disorder or Posttraumatic Stress Disorder. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.
3. Ghahramanlou-Holloway, M. (2013, May). The role of trauma in suicidal states. Invited presentation at Aeschi West: Basic Principles in Working with Suicidal Adults, Vail, CO.
4. Brown, G., & Ghahramanlou-Holloway, M. (2013, May). Cognitive behavior therapy for suicidal patients. Invited workshop at Aeschi West: Basic Principles in Working with Suicidal Adults, Vail, CO.

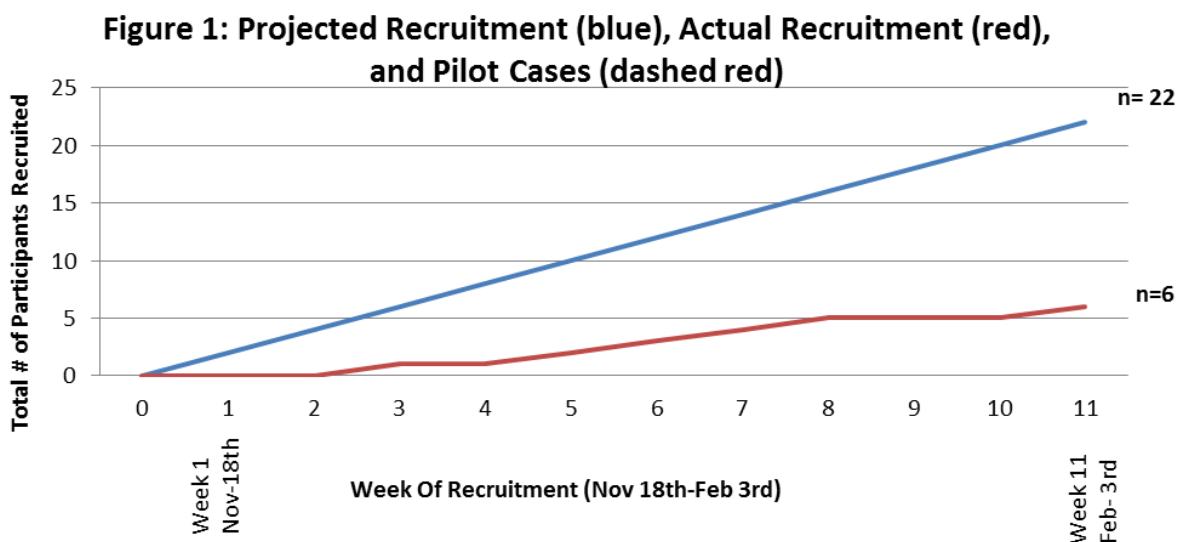
### *Conference Presentations and Abstracts*

1. MacIntyre, J., Perera, K., DeYoung, K., & Ghahramanlou-Holloway, M. (2013, April). Psychiatric inpatient trauma histories: An examination of documented trauma histories in military inpatients admitted for suicide ideation, suicide attempt, and non-suicide related events. Paper presented at the Annual Meeting of the American Association of Suicidology, Austin, TX.
2. Brown, G., K., Ghahramanlou-Holloway, M., & Green, K. L. (2013, April). Cognitive therapy for the prevention of suicide among military personnel and Veterans: Ongoing research and clinical recommendations. Symposium presented at the Annual Meeting of the American Association of Suicidology, Austin, TX.
3. Neely, L., Carreno-Ponce, J. T., Irwin, K., Perera, K., Grammer, G., & Ghahramanlou-Holloway, M. (2013, May). Post Admission Cognitive Therapy (PACT) for the prevention of suicide in military personnel with histories of trauma: Treatment development and case example. Poster presented at Aeschi West: Basic Principles in Working with Suicidal Adults, Vail, CO.
4. Neely, L. L., Irwin, K., Holloway, K., Perera, K., & Grammer, G., & Ghahramanlou-Holloway, M. (2013, August). Problem solving in suicidal service members: Clinical observations versus self-report. Breakout session presented at the Military Health System Research Symposium, Ft. Lauderdale, FL.
5. Carreno-Ponce, J. T., & Ghahramanlou-Holloway, M. (2013, August). Current intervention evaluations underway: The "SafeMil" and "PACT" randomized controlled trials at WRNMMC. Breakout session presented at the Military Health System Research Symposium, Ft. Lauderdale, FL.

## Preliminary Data

Formal recruitment for the study, at the Walter Reed National Military Medical Center (WRNMMC) and the Fort Belvoir Community Hospital (FBCH), began on November 18, 2013. Prior to this start date (during the months of August to November 2013), a total of 4 participants were recruited as pilot cases.

The Consolidated Standards of Reporting Trials (CONSORT) flow diagram is provided in Appendix C and provides a detailed outline of flow of participants into the trial. From November 18, 2013 to February 3, 2013 (i.e., 11 weeks), a total of 181 individuals were admitted to WRNMMC and FBCH for suicide-related reasons. Of these individuals, 17 (9%) were referred and approached for consent following expressed interest to hear more about the study. A total of 11 out of 17 (65%) individuals referred and approached for consent, agreed to participate in the study. A total of 5 out of 17 individuals (29%) declined the invitation to participate. Overall, 2 consented individuals were discharged from the unit prior to randomization, thus only 9 participants were randomized into study conditions. During this 11-week period of open enrollment, the rate of recruitment has been approximately 1 participant every 12 days. Our originally estimated plan was to have 2 participants from all sites every 7 days. Based on the lower than expected recruitment rate, we continue to consider and implement a number of strategies to increase our recruitment numbers.



**Table 1. Demographic Characteristics of Sample (N = 8)\*<sup>1</sup>**

	<b>EUC (n = 3)</b>	<b>PACT + EUC (n = 5)</b>
Age, mean (SD), years	25.7 (10.7)	28.6 (8.0)
<b>Gender</b>		
Male	2 (66.7)	4 (80.0)
Female	1 (33.3)	1 (20.0)
<b>Race</b>		
American Indian/Alaska Native	0	1 (20.0)
Asian	0	0
Black/African-American	0	0
White	3 (100.0)	3 (60.0)
Two or more	0	1 (20.0)
Other	0	0
<b>Ethnicity</b>		
Hispanic/Latino	0 (0.00)	3 (60.0)
Not Hispanic/Latino	3 (100.0)	2 (40.0)
<b>Education</b>		
High school diploma/equivalent	0	2 (40.0)
Some college, no degree	3 (100.0)	3 (60.0)
Higher studies	0	0
<b>Military Rank</b>		
E1 - E4	2 (66.7)	1 (20.0)
E5 - E9	0	4 (80.0)
Officer (O1 - O10)	0	0
Warrant Officer (W1 – W5)	1 (55.6)	0
Civilian	0	0
<b>Marital Status</b>		
Single	2 (66.7)	1 (20.0)
Married	1 (55.6)	2 (40.0)
Separated/Divorced/Widowed	0	1 (20.0)

*\* Data presented as No. (%), except as noted*

<sup>1</sup> Data as of February 3<sup>rd</sup>, 2014. A total of 11 participants consented to participate in the study. Two participants were discharged before baseline assessment and randomization, and one participant's data had not yet been entered into the database. Therefore, totals reflect only the 8 randomized participants with entered data.

**Table 2. Clinical Characteristics of Sample (N=8)\*<sup>2</sup>**

	<b>EUC (n = 3)</b>	<b>PACT + EUC (n = 5)</b>
<b>Suicide Attempts</b>		
None	0	0
Once	1 (33.3)	2 (40.0)
Twice	0	1 (20.0)
Thrice or more	2 (66.7)	2 (40.0)
Unknown	0	0

*\* Data presented as No. (%)*

**Table 3: Baseline Symptomatology (N = 8)**

	<b>Baseline</b>
<b>Scale for Suicide Ideation (SSI) - current</b>	<b><i>M (SD)</i></b>
EUC	4 (6.9)
PACT + EUC	4.8 (8.0)

**Table 4: Summary of Adverse Events**

<b><u>Type of Serious AE</u></b>	<b><u>EUC</u></b>	<b><u>PACT + EUC</u></b>	<b><u>Total</u></b>
Expected but possibly related	0	0	0
Unexpected but unlikely related	0	0	0
Unexpected and possibly related	0	0	0

*Note: Table includes all self-reported or clinician-reported serious adverse events reported to PACT study staff during assessments and intervention contacts.*

<sup>2</sup> Data as of February 3<sup>rd</sup>, 2014. A total of 11 participants consented to participate in the study. Two participants were discharged before baseline assessment and randomization, and one participant's data had not yet been entered into the database. Therefore, totals reflect only the 8 randomized participants with entered data.

## Conclusion

There are no study findings to report at the present time. The third year of the study has continued to heavily focus on the following activities: (1) obtaining appropriate regulatory approvals; (2) setting up the infrastructure for the study implementation at the two study sites (Walter Reed National Military Medical Center and Fort Belvoir Community Hospital); (3) selecting, hiring, and training study personnel; (4) finalizing the study assessment batteries for baseline and follow-up and collaborating with KAI on the design of web-based data forms; (5) coordinating and communicating with sites about study setup; (6) clarifying credentialing and staff start-up procedures at each military treatment facility; (7) recruiting members, setting up, and completing the first Data Safety Monitoring Board meeting, (8) developing the study master database and finalizing randomization procedures, (9) finalizing the standard operating procedures for case management, assessment, and risk management, and (10) initiation of study enrollment, work with pilot cases, and conduct of initial follow-up assessments.

The early study conclusions are that at least 12-18 months need to be devoted to obtaining regulatory approvals for research pertaining to suicidal individuals receiving treatment at a military treatment facility. In addition, credentialing issues at various military treatment facilities such as WRNMMC and FBCH for research personnel appear to remain unclear and present unique implementation and financial challenges for suicide prevention research within the DoD setting. We have also learned that a change of leadership at inpatient psychiatric units may have an impact on implementation. In recent months, the WRNMMC inpatient psychiatric unit is focusing on a shorter length of stay for patients which makes it a challenge for our research team to deliver the study intervention to those randomized to the PACT condition.

This study is responsive to the critical mental health care needs of military service members by providing a targeted cognitive behavioral intervention for suicide ideation and behavior severe enough to warrant psychiatric hospitalization. The ultimate goal of the treatment is to prevent suicide and associated risk factors within a high risk group of the Armed Forces. Without adequate treatment, suicide related events leading to psychiatric hospitalization may result in costly utilization of military, VA, and civilian health and social services, a decrease in operational readiness and morale, human suffering, and eventual death.

Furthermore, this study is aligned with several critical research areas recognized by the US Research and Materiel Command: (1) reduction of the impact of mental disorders for the Armed Forces; (2) development of strategies to enhance mental health and well-being throughout service members' careers; (3) validation of effective psychotherapy interventions; (4) targeted evidence-based risk reduction methods for suicide behavior; (5) development of valid treatment related outcome measures and tracking systems; (6) reduction of barriers to care and appropriate linkage to healthcare services; and (7) special considerations for sub-populations with unique needs – for instance, those with combat trauma and/or Traumatic Brain Injury (TBI).

## References

None.

## Appendices

**Appendix A** – PACT DSMB Meeting 1 Minutes

**Appendix B** – PACT ClinicalTrials.Gov Receipt

**Appendix C** – PACT Consolidated Standards of Reporting Trials (CONSORT) Diagram



<b><u>Data Safety Monitoring Board Meeting #1</u></b>		
<b>Date</b>	November 15, 2013	
<b>Attendees</b>	<p><i>Present:</i>            Dr. Kate Comtois (DSMB Chair, Harborview Medical Center);            Dr. Thomas Ellis (DSMB Member, The Menninger Clinic);            Dr. David Goldston (Co-PI, Duke University);            Ms. Rene Kozloff (KAI, Inc.);            Ms. Celeste Crouse (KAI, Inc.);            Ms. Amy Price (KAI, Inc.);            Dr. Marjan Holloway (PI, Uniformed Services University of the Health Sciences);            Dr. Laura Neely (Clinical Coordinator, Uniformed Services University of the Health Sciences)</p> <p><i>Absent:</i>            Dr. Cara Olsen (DSMB Member, Uniformed Services University of the Health Sciences);            Dr. Cheryl King (Co-PI, University of Michigan)</p>	
<b>Agenda Items</b>	<ol style="list-style-type: none"> <li>1. Introduction</li> <li>2. Brief Overview of PACT</li> <li>3. Address questions and concerns of the DSMB members</li> <li>4. Review and approve DSMB template</li> <li>5. Next Meeting</li> </ol>	
<b><u>Topic</u></b>	<b><u>Critical Discussion</u></b>	<b><u>Final Decision &amp; Follow-Up Responsibility</u></b>
<b>1. Introduction</b>	<ul style="list-style-type: none"> <li>• Prior to the call, Dr. Holloway provided several supporting documents for each member of the DSMB to review. Documents included:               <ul style="list-style-type: none"> <li>○ IRB-Approved Study Protocol</li> <li>○ IRB-Approved Study Consent Form</li> <li>○ IRB Approval Notices</li> <li>○ Template of a Proposed DSMB Report</li> <li>○ Draft of DSMB Charter</li> </ul> </li> <li>• At the beginning of the call, the group decided on an agenda for the call, which included:               <ul style="list-style-type: none"> <li>○ PI to give general orientation to study</li> <li>○ Address questions and concerns of the DSMB members</li> <li>○ Review and approve DSMB template</li> <li>○ DSMB members to discuss and vote on continuation of study</li> <li>○ DSMB to submit feedback to USUHS in writing</li> </ul> </li> </ul>	

<b>2. Brief Overview of PACT</b>	<ul style="list-style-type: none"> <li>• Dr. Holloway provided a brief overview of PACT, which included descriptions of the purpose, primary and secondary outcomes, inclusion criteria, design, and intervention.</li> </ul>	
<b>3. Address questions and concerns of the DSMB members</b>	<ul style="list-style-type: none"> <li>• DSMB members were provided time to ask questions about the structure of the study.</li> <li>• Dr. Comtois requested clarification on who is providing the treatment at baseline and on the telephone. <ul style="list-style-type: none"> <li>○ Dr. Holloway gave a brief description of the research team members and the roles and responsibilities for each.</li> </ul> </li> <li>• Dr. Ellis asked for a brief description of provisions in place for a potential crisis on the telephone. <ul style="list-style-type: none"> <li>○ Dr. Holloway described the warm hand off process to be implemented with the Suicide Prevention Lifeline sponsored by the Veteran's Administration.</li> </ul> </li> <li>• Dr. Comtois requested clarification of the inclusion criteria – specifically the term used “preferable 24-48 hours.” <ul style="list-style-type: none"> <li>○ Dr. Holloway clarified that this language was chosen in order to limit protocol deviations.</li> </ul> </li> <li>• Dr. Comtois asked for clarification on the notification of random assignment and expressed concern over inflating the effect size.</li> <li>• Dr. Comtois gave the suggestion of not having the follow-up assessors test the blind after every assessment.</li> <li>• Dr. Comtois requested clarification on what information is disclosed to the treatment team and when.</li> </ul>	<ul style="list-style-type: none"> <li>• Remove sentence from consent form.</li> <li>• Do not tell participant that the baseline assessor will also be the PACT clinician before random assignment.</li> <li>• Train research team by writing a script and inserting into SOP.</li> <li>• Dr. Goldston to test follow-up assessors once a year.</li> <li>• Create a single flag within the tracking system in the event a follow-up assessor becomes unblinded.</li> <li>• Update the protocol and consent form to clarify and be more consistent regarding disclosure of imminent risk.</li> </ul>
<b>4. Review and approve DSMB template</b>	<ul style="list-style-type: none"> <li>• Dr. Holloway gave a brief overview of the DSMB report template.</li> <li>• The DSMB members approved the structure of the CONSORT, tables, and overall template.</li> </ul>	<ul style="list-style-type: none"> <li>• In the event that recruitment is delayed, include a list of all recruitment strategies implemented to</li> </ul>

		<p>address this as well as any analysis of the problem and possible solutions.</p> <ul style="list-style-type: none"> <li>• Present AE data by blinded group, DSMB members can request more information as needed.</li> </ul>
<b>5. Next Meeting</b>	<ul style="list-style-type: none"> <li>• Research team members stepped off the call; DSMB members voted on the continuation of the study.</li> <li>• It was decided that the USUHS research team will send an updated report in 3 months, on <b>February 14, 2014</b>.</li> <li>• At that time, the DSMB members will decide if a meeting is warranted.</li> </ul>	<ul style="list-style-type: none"> <li>• DSMB members will email final decision to research team.</li> <li>• Research team to email meeting minutes to DSMB members for approval.</li> <li>• Meeting minutes and approval letter will be submitted to WRNMMC IRB at the time of continuing review.</li> </ul>

**\*\*\*UPDATE:** On November 18, 2013, the DSMB Chair, Dr. Kate Comtois, emailed the PI, Dr. Marjan Holloway, and the USUHS research team and gave approval to begin formal recruitment.

Protocol Registration Receipt

10/25/2013

Post Admission Cognitive Therapy (PACT) for the Inpatient Treatment of Military Personnel With Suicidal Behaviors

This study is not yet open for participant recruitment.

Verified by Marjan Holloway, Henry M. Jackson Foundation for the Advancement of Military Medicine,  
October 2013

Sponsor:	Henry M. Jackson Foundation for the Advancement of Military Medicine
Collaborators:	Department of Veterans Affairs Duke University University of Michigan University of Pennsylvania Walter Reed National Military Medical Center Fort Belvoir Community Hospital
Information provided by (Responsible Party):	Marjan Holloway, Henry M. Jackson Foundation for the Advancement of Military Medicine
ClinicalTrials.gov Identifier:	NCT01359761

► Purpose

This study will implement and empirically evaluate the efficacy of a cognitive behavioral intervention program, titled, Post Admission Cognitive Therapy(PACT), for military service members admitted for inpatient care due to severe suicide ideation and/or a recent suicide attempt.

Condition	Intervention	Phase
Suicide, Attempted Suicidal Ideation Active	Behavioral: Post Admission Cognitive Therapy (PACT)	N/A

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Single Blind (Outcomes Assessor), Randomized, Safety/Efficacy Study

Official Title: Post Admission Cognitive Therapy (PACT) for the Inpatient Treatment of Military Personnel With Suicidal Behaviors: A Multi-Site Randomized Controlled Trial

Further study details as provided by Marjan Holloway, Henry M. Jackson Foundation for the Advancement of Military Medicine:

Primary Outcome Measure:

- Repeat Suicide Attempts [Time Frame: 1, 3, 6, and 12 months] [Designated as safety issue: Yes]  
Repeat suicide attempts will be assessed using the Columbia Suicide Severity Rating Scale (C-SSRS), which assesses for number of subsequent suicide attempts.

Secondary Outcome Measures:

- Depression [Time Frame: 1, 3, 6, and 12 months] [Designated as safety issue: No]  
The Beck Depression Inventory-II (BDI-II) will be used to assess for symptoms of depression.
- Hopelessness [Time Frame: 1, 3, 6, and 12 months] [Designated as safety issue: No]  
The Beck Hopelessness Scale (BHS) will be used to assess for levels of hopelessness.
- Suicide Ideation [Time Frame: 1, 3, 6, and 12 months] [Designated as safety issue: No]  
The Scale for Suicide Ideation (SSI) will be administered to assess for suicide-related thoughts (ideation), as well as the frequency, intensity, and specificity of these thoughts.
- Post-Traumatic Stress Symptoms [Time Frame: 1, 3, 6, and 12 months] [Designated as safety issue: No]  
The Clinician Assessment of PTSD Scale (CAPS) and the PTSD Checklist (PCL) will be administered to assess for post-traumatic stress symptoms.
- Acceptability of Treatment [Time Frame: 1, 3, 6, and 12 months] [Designated as safety issue: No]  
Acceptability of treatment will be assessed by using Barriers to Care Items.
- Repeat Psychiatric Hospitalizations [Time Frame: 1, 3, 6, and 12 months] [Designated as safety issue: No]  
Subsequent psychiatric hospitalizations will be assessed for using the Cornell Services Index (CSI), as well as by accessing the Defense Medical Surveillance System (DMSS), which contains electronic medical records of all military personnel (permission to access participants' DMSS records is given at time of consent).

Estimated Enrollment: 218

Study Start Date: November 2013

Estimated Study Completion Date: October 2017

Estimated Primary Completion Date: October 2017

Arms	Assigned Interventions
Experimental: Post Admission Cognitive Therapy (PACT) Six (6) 60-90 Minutes Post Admission	Behavioral: Post Admission Cognitive Therapy (PACT) Six (60-90 minutes) individual psychotherapy sessions administered over preferably 3 days of inpatient stay,

Arms	Assigned Interventions
Cognitive Therapy Individual Sessions; Up to Two (2) Inpatient Booster Sessions; Up to Four (4) Telephone Booster Sessions Following Psychiatric Discharge; 12-Months Case Management	up to 2 booster sessions during hospitalization, and 4 telephone booster sessions within 3-months post discharge  Other Names: Cognitive Therapy Cognitive Behavior Therapy
No Intervention: Enhanced Usual Care (EUC) Treatment As Usual and Study Assessment Services; 12-Months Case Management	

Background: Suicide remains a serious national public health problem and has become a leading cause of death in the United States military. To date, there is no evidence-based civilian or military inpatient interventions aimed at the reduction of suicide behavior. Our proposal addresses this important gap and aims to evaluate an innovative suicide intervention, Post Admission Cognitive Therapy (PACT). Left untreated, severe suicide ideation and/or suicide attempts that require psychiatric hospitalization may place an individual at a lifetime risk for increased psychopathology, subsequent suicide behavior, and death.

Objective: The broad objective is to implement and empirically evaluate the efficacy of a cognitive behavioral intervention program, titled Post Admission Cognitive Therapy (PACT), for military service members admitted for inpatient care due to severe suicide ideation (with lifetime history of suicide attempt) and/or a recent suicide attempt.

Specific Aims: To evaluate the efficacy of PACT plus Enhanced Usual Care (EUC) versus EUC for the prevention of suicide in psychiatrically hospitalized military personnel at follow-up (1, 3, 6, and 12-month) on (1) incidence of repeat suicide attempt(s) and number of days until a repeat suicide attempt (primary outcomes), and (2) psychiatric symptoms (depression, trauma, sleep, suicide ideation), repeat number of psychiatric hospitalization(s), hope for one's future, and acceptability of treatment (as measured by time to linkage to specialty care, attitudes toward seeking help for mental health issues, and subsequent mental health service utilization) (secondary outcomes). The investigators expect that adults in the PACT+EUC (experimental) condition compared to those in the EUC (control) condition will show favorable outcomes on both primary and secondary measures.

Study Design: The research design is a multi-site, single-blind, randomized controlled trial (RCT). A total of 218 individuals who are over the age of 18, able to communicate in English and willing to provide informed consent will be recruited from the inpatient psychiatric units at the Walter Reed Army Medical Center and the Naval Medical Center Portsmouth. Participants will be randomized into one of two conditions: (1) [Post Admission Cognitive Therapy (PACT) + Enhanced Usual Care (EUC)] or (2) Enhanced Usual Care (EUC). Individuals randomized into PACT+EUC will participate in the study assessments, receive six 60-90 minute individual face-to-face PACT psychotherapy sessions provided during their inpatient stay, up to a maximum of four 30-minute phone PACT booster sessions during the 3 months post hospital discharge, and case management services for 12 months. Individuals randomized into the control condition (EUC) will not receive the study intervention; they will receive the usual care provided in the inpatient setting, participate in study assessments,

and receive case management services for 12 months. Patients in both conditions will be assessed on the dependent measures at baseline and at 1-, 3-, 6-, and 12-month follow-up intervals.

Relevance: Delivering a brief and possibly potent psychotherapeutic intervention during a psychiatric inpatient hospitalization followed by an aftercare component aims to directly target individuals at high risk for future suicide behavior, specifically young, psychiatrically hospitalized adults under the direct stress of a military career. The development and empirical validation of an inpatient cognitive behavioral treatment is a significant endeavor in our national as well as Department of Defense (DoD) suicide prevention efforts. If Post Admission Cognitive Therapy is found to be efficacious, the intervention can be subsequently disseminated to inpatient settings as the standard of care for military personnel and beneficiaries admitted for suicide-related events.

## Eligibility

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Both

Inclusion Criteria:

- Suicide Ideation + Prior Attempt OR Recent Suicide Attempt
- Baseline Completed within Preferably 48-72 Hours of Admission
- Over the Age of 18
- Provides Informed Consent

Exclusion Criteria:

- Medical Incapacity to Participate
- Serious Cognitive Impairment
- Expected Discharge within 72 Hours of Admission

## Contacts and Locations

### Contacts

Marjan G Holloway, Ph.D.	301-295-3271	marjan.holloway@usuhs.edu
Laura Neely, Psy.D.	301-295-4158	laura.neely.ctr@usuhs.edu

### Locations

#### United States, Maryland

Walter Reed National Military Medical Center  
Bethesda, Maryland, United States, 20815  
Uniformed Services University of the Health Sciences  
Bethesda, Maryland, United States, 20814

#### United States, North Carolina

Duke University  
Durham, North Carolina, United States, 27708

#### United States, Virginia

Fort Belvoir Community Hospital

Fort Belvoir, Virginia, United States, 22060

## Investigators

Principal Investigator: Marjan G Holloway, Ph.D.

Uniformed Services University  
of the Health Sciences

## More Information

Responsible Party: Marjan Holloway, Principal Investigator, Henry M. Jackson  
Foundation for the Advancement of Military Medicine

Study ID Numbers: W81XWH-11-2-0106

Health Authority: United States: Federal Government  
United States: Institutional Review Board



## Enrollment



# **Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram for PACT**

## **Reasons Patients Declined to Enroll (n = 5)**

D1: Patient stated that it would be too difficult to talk about.

D2: Patient denied SI/SA and did not think that he would be able to complete the follow up assessments.

D3: Patient reported concern about the amount of time needed to dedicate to the study while on the unit and about being overwhelmed by the combination of FBCH usual care with PACT if randomized to treatment.

D4: Patient did not want to take time to complete baseline assessment if there was only a 50/50 chance of getting treatment. Patient was also uncomfortable with the idea of completing phone contacts and assessments.

D5: Patient felt that the study would take too much time.

## **Reasons Patients Decided to Withdraw (n = 1)**

W1: Patient asked to withdraw during phone call with follow-up assessor. Patient did not provide reason for requesting to withdraw.